EUROPEAN COMMISSION

Brussels, 5.9.2011
C(2011)6369 final

COMMISSION IMPLEMENTING DECISION

of 5.9.2011

amending the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 5.9.2011

amending the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the notification submitted by Sanofi-Aventis Deutschland GmbH, under Article 15(1) of Regulation (EC) No 1234/2008,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the minor variation of type IB, notified between 8 December 2010 and 26 July 2011, and of the need to amend the decision granting the marketing authorisation.

(2) The marketing authorisation should be updated and Decision C(2004)3653 of 27 September 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

---

1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.

(3) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3653 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Decision C(2004)3653 is amended as follows:

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/557/IB/34	C.I.3.a) (EU/1/04/285/001-036)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, on 5.9.2011. 5.9.2011.

For the Commission
Paola TESTORI COGGI
Director-General